

REMARKS

The Office Action mailed October 18, 2002 has been carefully reviewed and the foregoing amendment is made in response thereto. Applicants respectfully submit that no prohibited new matter has been introduced by the amendment. Support for the amendment to claim 15 can be found throughout the specification, for example, at page 2, lines 14-24, and in Example 1 on page 6.

In view of the amendment and the following remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

I. Summary of the Office Action

1. The Examiner objected to claims 15-20 for not being specifically drawn to the elected group.
2. The Examiner rejected claims 15-20 under 35 U.S.C. §112, 2nd paragraph as being indefinite for being dependent upon a non-elected claim.
3. The Examiner rejected claims 15-20 under 35 U.S.C. §103(a), as being unpatentable over Haigwood *et al.* in view of Cates *et al.*
4. No claims were allowed.

II. Response to the Office Action

Objection to claims 15-20 for not being drawn to the elected group

Claim 15 has been amended to bodily incorporate the subject matter of claim 13 and specifically recites modified V3 loop of the HIV-1 envelope protein. Accordingly, the claims are no longer informal and withdrawal of the ground of objection is respectfully requested.

Rejection of claims 15-20 under 35 U.S.C. §112, 2nd paragraph as being indefinite

As stated *supra*, claim 15 has been amended to bodily incorporate the subject matter of claim 13 and specifically recites modified V3 loop of the HIV-1 envelope protein. Accordingly, Applicants respectfully request withdrawal of the ground of rejection.

Rejection of claims 15-20 under 35 U.S.C. §103(a), as being unpatentable over U.S. Patent 5,792,459 to Haigwood *et al.* in view of U.S. Patent 6,309,649 to Cates *et al.*

The Office Action contends that the claimed invention is obvious over the combined references because the '459 patent "provides HIV-1 envelope muteins in which various portions of the V3 loop are deleted." The '649 patent is relied upon in the Office Action for teaching pharmaceutically acceptable adjuvants. The Applicants respectfully traverse the ground of rejection as it is applied to the instant invention as presently claimed. The '459 patent is drawn to HIV-1 envelope analogs (muteins) comprising all of the constant domains C1-C5 of gp120env or gp160env, but lacking at least one epitope from a hypervariable domain; said analogs are useful as antigens in raising nonisolate-specific antibodies upon immunization of a mammal. It is generally disclosed (for example at column 6, lines 1-10) that the deletions will typically be at least about one-third of a variable domain, and oftentimes will consist of a deletion of an entire variable domain. The '459 patent does not, however, teach the specified deletions within the V3 loop domain as required by the presently claimed invention. More specifically, the presently claimed invention is drawn to a vaccine composition comprising a mutated V3 loop of the envelope protein, wherein the mutation comprises deleting the amino acid sequence between the Cys residue at the amino terminal end of the loop and the GPGRF hexamer at the top of the loop and the amino acid sequence between said GPGRF hexamer at the top of the loop and the Cys residue at the carboxyl terminal end of the loop. Accordingly, the '459 patent cannot render the instant invention as presently claimed obvious either on its own or in combination with the '649 patent. Accordingly, Applicants respectfully request withdrawal of the ground of rejection.

Conclusion

In view of the foregoing remarks, the Applicants respectfully request withdrawal of all outstanding rejections and early notice of allowance to that effect.

EXCEPT for issue fees payable under 37 C.F.R. § 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-0310. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F.R. § 1.136(a)(3).

If the Examiner finds that a telephone conference would further prosecution of this application, she is invited to call the undersigned.

Respectfully submitted,
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APPENDIX A

Marked-Up Copy of Amended Claims

[~~deleted text~~]; added text

15.(Amended) A vaccine composition comprising a recombinant HIV-1 envelope protein [~~according to claim 13~~] comprising a mutated V3 loop, wherein the mutated V3 loop consists of the GPGRAPH (SEQ ID NO: 1) hexamer sequence flanked by the two basal cysteines, and at least one pharmaceutically acceptable vehicle.